

3.0 510(k) Summary

DEC 5 2005

Page 1 of 1

Sponsor: Synthes (USA)
1302 Wrights Lane East
West Chester, PA 19380
(610) 719-5000

Device Name: Synthes Sternal Fixation System

Classification: 21 CFR 888.3030: Plate, fixation, bone, non-spinal

Predicate Devices: Synthes Sternal Fixation Systems

Device Description: The Synthes Titanium Locking Plates feature compression screw holes which accept existing 2.4 and 3.0mm locking screws, have notched sides and undersides. The plates are available in lengths of 96 and 160mm with 12 and 20 holes.

Intended Use: The Synthes Sternal Fixation System is intended for use in primary or secondary closure/repair of the sternum following sternotomy or fracture of the sternum to stabilize the sternum and promote fusion.

CONTRAINDICATIONS
The Synthes Titanium 2.4mm Universal Locking Plates are contraindicated for use in acute cardiac patients.

**Substantial
Equivalence:** Information presented supports substantial equivalence.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 5 2005

Lisa Boyle
Regulatory Specialist
Synthes (USA)
1302 Wrights Lane East
West Chester, Pennsylvania 19380

Re: K052683

Trade/Device Name: Synthes Sternal Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation
appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: November 2, 2005
Received: November 9, 2005

Dear Ms. Boyle:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), they may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your devices as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your device and thus, permits your devices to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



K052683

Page 1 of 1

2.0

Indications for Use

510(k) Number (if known): K052683

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Indications for Use:

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CONTRAINDICATIONS

The Synthes Titanium 2.4mm Universal Locking Plates are contraindicated for use in acute cardiac patients.

Prescription Use X AND/OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K052683